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# Bescheinigung | Certificate | Attestation

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The attached documents are exact copies of the European patent application described on the following page, as originally filed.

Les documents fixés à cette attestation sont conformes à la version initialement déposée de la demande de brevet européen spécifiée à la page suivante.

**Patentanmeldung Nr. | Patent application No. | Demande de brevet n°**

00610052.3

Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.

I.L.C. HATTEN-HECKMAN

DEN HAAG, DEN
THE HAGUE, 14/12/00
LA HAYE, LE

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# Blatt 2 der Bescheinigung
# Sheet 2 of the certificate
# Page 2 de l'attestation

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Needle assembly with movable safety sheath

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# Needle assembly with movable safety sheath

The invention relates to a needle assembly, which reduces the risk of accidental needle-stick injuries, and especially safety needle assemblies where a needle cannula is mounted in a hub.

Needle assemblies are commonly used to both inject substances into and extract substances out of human and animal bodies. Such needle assemblies are typically disposable and are discarded after only one use. The problem presented by the disposal of a needle assembly, and indeed, by any handling of the needle assembly, is the potential risk for being injured by the sharp end of the needle. This is particular dangerous when following after the perforation of a patients skin since the needle assembly then may be contaminated and therefore capable of spreading diseases, such as hepatitis and HIV.

A great number of needle assemblies have been described that provides protection for the professionals who use injection needle assemblies in their daily work. In many of these known solutions an axially movable shield or sheath is provided surrounding the needle cannula, which sheath can be shifted between a first position where the sheath covers the needle cannula and a second position where the needle cannula is exposed and ready for injection.

Such a prior art needle assembly is shown in WO 95/21646. In this prior art needle assembly the needle cannula and the hub is contained inside a tubular sleeve. The hub carrying the needle cannula can be moved between a first position where the needle is fully retracted into the tubular sleeve, and a second position where the needle cannula goes beyond the distal end of the tubular sleeve. A projection located on the hub is guided in a predetermined way in a track provided in the tubular sleeve.

Another prior art needle assembly is shown in EP 268.445. This publication shows a needle assembly where a needle cannula supported by a hub is removable attached to an injection syringe. A sheath is movable mounted inside the hub and can be slided from a retracted first position where the sheath fully covers the needle cannula thereby preventing accidental needle stick injuries, to a second position where the needle cannula is ready for use. A spring is provided between the sheath and the hub, which spring forces the sheath towards the first position where the sheath covers the needle cannula when no pressure is applied to the sheath. In order to prevent reuse of the needle assembly and to secure the needle can-

nula in the first position after use a lock between the hub and the sheath is provided. This lock is made from a projection provided on the sheath and a hooked portion provided in a guiding track in the hub. When the sheath is moved into the second position the projection automatically drops into the hooked portion of the track thereby locking the sheath in respect to the hub.

In order to prevent infections of the skin it is of the outmost importance to keep the needle cannula sterile at all times prior to use, the known needle assemblies are therefore always delivered packed in an exterior package.

The needle assembly known from EP 268.445 has the movable sheath fastened inside the hub, leaving an open clearance between the sheath and the hub. This clearance cannot be sealed properly because the sheath has to be movable. It is therefore impossible to keep the compartment containing the needle cannula sterile. This known needle assembly therefore has to be delivered to the user in an exterior package.

The needle assembly known from WO 95/21646 also has to be contained in an exterior package, while the guiding track is penetrating the sidewalls of the tubular sleeve, thereby exposing the interior of the tubular sleeve to the atmosphere.

It is an object of the present invention to provide a needle assembly, which do not posses the drawbacks of the prior art needle assemblies, and where it is possible to house the hub and the needle cannula inside the sheath and to keep the compartment inside the sheath containing the needle cannula sterile at all times prior to use.

This is obtained by a needle assembly with a needle cannula mounted in a hub for removable connection with an injection device, having a first distal end for piercing the skin of a patient and a second proximal end for entering said injection device, comprising;

a hub and a sheath which can move relatively to each other, said sheath surrounding said needle cannula and having a proximal end and a distal end which distal end allows passage of the needle cannula, said sheath being mounted upon said hub for slidable movement relative thereto between a first position in which both said hub and said needle cannula is fully contained inside the boundaries of said sheath and a second position which permits normal use of the needle cannula, and

guiding tracks in which a projection is being guided in a predetermined way, said guiding tracks and said projection being provided on opposite parts of said hub and said sheath

Which needle assembly according to the invention is characterized in that said sheath is impermeable and that said distal end of said sheath and said proximal end of said sheath is sealed by a barrier.

By making the sheath impermeable and covering the distal and the proximal openings with a barrier, it is ensured that the interior of the sheath stays sterile after sterilization and until the barrier is broken when the needle assembly is used for its purpose. Since the sheath is now the container in which the hub and the needle cannula is contained there is no use for an exterior package, and the needle assembly can be delivered to the user simply contained in the sheath.

When, as disclosed in claim 2, the barrier is an impermeable pealable sheet and that the interior of the sheath is sterile until the impermeable pealable sheet is broken, it is ensured that the barrier can easily be removed. The pealable sheet can be made of paper or from a polymeric or metallic sheet, and is preferably glued, melted or welded on to the sheath. Although the barrier is impermeable, it is possible to sterilize the interior of the sheath.

When, as disclosed in claim 3, locking means for locking the sheath in the first position is provided, which locking means comprises at least one aperture located in the track and into which aperture the projection automatically locks when the sheath is brought back into the first position after use, it is ensured that the needle assembly can not be reused once the sheath is brought back into the first position after use.

When, as disclosed in claim 4, the guiding track is provided on the inside surface of the sheath and the projection is provided on the outside surface of the hub it is ensured that the hub and the sheath can be easily manufactured.

When, as disclosed in claim 5, the projection is carried on a resilient arm, it is ensured that the hub can be easily inserted into the sheath.

When, as disclosed in claim 6, the guiding track comprises a first part being parallel to the needle cannula and a second part being connected to the first track at an acute angle, and

as disclosed in claim 7, the projection can be shifted between three different locations in said guiding track, a first location being one where the sheath is in the first position, and the needle cannula is covered by the sheath, which sheath is longitudinal movable, a second location of the projection being one where the sheath is in the second position and the needle cannula is exposed, and a third location being one where the sheath is irreversible locked in the first position, it is ensured that the projection can slide in one track when the sheath is pushed backwards and in the other track when the sheath is pushed forward.

When, as disclosed in claim 8 the guiding track has at least one aperture with a steep front preventing the projection from moving backwards in the guiding track when the projection has entered the second or/and the third location, or as disclosed in claim 9 the guiding track is provided with at least one resilient arm preventing the projection from moving backwards in the guiding track when the projection has entered the second location or/and the third location, it is ensured that the projection can only move forward in one direction between the various positions in the guiding track, and the used needle assembly is irreversibly locked after the projection is brought into the third position thereby rendering the needle assembly unusable.

When, as disclosed in claim 10 a helical spring is provided between the hub and the sheath biasing the sheath towards the first position when no force is exerted on the sheath, it is ensured that the movement of the sheath is done automatically by the influence of the helical spring. When inserting the needle cannula into the skin of the patient the sheath is pushed back by the force exerted on the sheath, and when the needle cannula is withdrawn form the skin of the patient, the sheath is automatically urged back into the first position by the helical spring.

The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawings in which:

| | |
|---|---|
| Figure 1 | Shows a sectional view of the needle assembly according to the invention. |
| Figure 2 | Shows a sectional view of the needle assembly according to an embodiment of the invention. |

Figure 3 A, B, C — Shows a perspective view of different hubs carrying the needle cannula.

Figure 4 A, B, C — Shows the projection on the hub in three different locations in the guiding track provided in the sheath.

Figure 5 — Shows an alternative embodiment of the guiding track.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals are used for identical or corresponding parts.

Figure 1 shows the needle assembly prior to use. The needle cannula 1 is mounted in the hub 2. The needle cannula 1 has a distal end for piercing the skin of a patient and a proximal end for piercing the elastomeric seal of a cartridge carried in the injection device onto which the needle assembly is mounted.

The sheath 3, which is usually made from a suitable polymeric material, has at the distal end a tiny hole 4, which allows passage of the needle cannula 1. At the proximal end the sheath 3 is provided with a larger hole or cavity 5 into which the hub 2 is fitted.

Both the hub 2 and the needle cannula 1 fastened to the hub 2 are contained inside the boundaries of the sheath 3. The top surface and the bottom surface of the sheath 3 is both sealed by a pealable sheet 6, 7, which can be impermeable. Since the sheath 3 has no other openings the interior hereof can be kept sterile until either of the pealable seals 6, 7 is broken.

The sheath 3 is moved manually between the first position and the second position by the user. But the needle assembly can however be provided with a spring 8 positioned between the hub 2 and the sheath 3 urging the sheath 3 away from the hub 2, as shown in figure 2. This spring 8 makes the operation of the sheath 3 automatic as will be explained later.

The sheath 3 is connected to the hub 2 by a projection 9 located on the outside surface of the hub 2, and being guided in a guiding track 10 located on the inside surface of the sheath

3. The projection 9 is as shown in figure 3 A, B and C provided on a small resilient arm 11 thereby making the projection 9 somewhat resilient.

The guiding track 10 is provided on the inside surface of the sheath 3 and guides the projection 9 and thereby the hub 2 relatively to the sheath 3. This guiding track 10 is actually made up from two parts, a first part extending parallel to the needle cannula 1, and a second part connected to the first part at an acute angle.

In use the needle assembly is first mounted onto the not shown injection device e.g. by screwing the hub onto the injection device utilising the thread 12 of the hub 2. Initially the projection 9 is located in the first location, which is in the first part of the guiding track 10 as shown in figure 4A. The edges of the track 10 can be provided with a number of barbs 13 holding the projection 9 in this starting location.

The sheath 3 is then pulled back towards the not shown injection device to uncover the needle cannula 1 either manually or by the force exerted on the sheath 3 when the needle cannula 1 penetrates the skin, as shown in figure 4B. In this second location the bottom wall of the track 10 is lowered a little, leaving the bottom wall with a steep front 14, which prevents the projection 9 from moving back into the first position.

During the retraction of the needle cannula from the skin the spring-acted sheath 3 is automatically moved forward by the spring 8 when the pressure applied to the end portion of the sheath 3 is released. If no spring is provided, the sheath is manually moved forward. When the sheath 3 is moved forward, the projection 9 enters its third location shown on figure 4C. In this third location the bottom wall of the track is lowered once again, leaving the bottom wall with yet another steep front 15. This steep front 15 prevents the projection 9 from moving back into any previous locations thereby rendering the needle assembly locked and unusable.

Figure 5 shows an alternative guiding track 10 where the steep fronts 14, 15 is replaced by small resilient arms 16, 17, which arms 16, 17 prevents the projection 9 from moving backwards in the guiding track 10.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

Claims

1. A needle assembly with a needle cannula mounted in a hub for removable connection with an injection device, having a first distal end for piercing the skin of a patient and a second proximal end for entering said injection device, comprising

a hub and a sheath which can move relatively to each other, said sheath surrounding said needle cannula and having a proximal end and a distal end which distal end allows passage of the needle cannula, said sheath being mounted upon said hub for slidable movement relative thereto between a first position in which both said hub and said needle cannula is fully contained inside the boundaries of said sheath and a second position which permits normal use of the needle cannula, and

guiding tracks in which a projection is being guided in a predetermined way, said guiding tracks and said projection being provided on opposite parts of said hub and said sheath

characterized, in that said sheath is impermeable and that said distal end of said sheath and said proximal end of said sheath is sealed by a barrier.

2. A needle assembly according to claim 1, characterized in that the barrier is an impermeable pealable sheet and that the interior of said sheath is sterile until the impermeable pealable sheet is broken.

3. A needle assembly according to claim 1 or 2, characterized in that locking means for locking said sheath in said first position is provided, which locking means comprises at least one aperture located in said track and into which aperture said projection automatically locks when said sheath is brought back into said first position after use.

4. A needle assembly according to anyone of the claims 1-3, characterized in that said guiding track is provided on the inside surface of said sheath and said projection is provided on the outside surface of said hub.

5. A needle assembly according to anyone of the claims 1-4, characterized in that said projection is carried on a resilient arm.

6. A needle assembly according to anyone of the claims 3 to 5, characterized in that said guiding track comprises a first part being parallel to said needle cannula and a second part being connected to said first track at an acute angle

7. A needle assembly according to anyone of the claims 3 to 6, characterized in that said projection can be shifted between three different locations in said guiding track;

a first location being one where said sheath is in said first position, and the needle cannula is covered by said sheath, which sheath is longitudinal movable,

a second location of said projection being one where said sheath is in said second position and the needle cannula is exposed, and

a third location being one where said sheath is irreversible locked in said first position.

8. A needle assembly according to claim 7, characterized in that said guiding track has at least one aperture with a steep front preventing said projection from moving backwards in said guiding track when said projection has entered said second or/and said third location.

9. A needle assembly according to claim 7, characterized in that said guiding track is provided with at least one resilient arm preventing said projection from moving backwards in said guiding track when said projection has entered said second location or/and said third location.

10. A needle assembly according to anyone of the preceding claims, characterized in that a helical spring is provided between said hub and said sheath biasing said sheath towards said first position when no force is exerted on said sheath.

ABSTRACT

A needle assembly with a needle cannula mounted in a hub for removable connection with an injection device. The needle assembly has a hub and a sheath, which can move relatively to each other. The sheath is impermeable and surrounds both the hub and the needle cannula. A barrier keeping the interior of the sheath sterile seals the distal end and the proximal end of the sheath. When the barrier is broken and the needle cannula is mounted on the injection device, the sheath can be slided from a first position in which both the hub and the needle cannula is fully contained inside the boundaries of said sheath to a second position which permits normal use of the needle cannula. The sheath may also include a guiding track for guiding a projection located on the hub in a predetermined way. The guiding track is preferably provided with at least one aperture into which the projection automatically locks when the sheath is brought back into the first position after use.

1/4

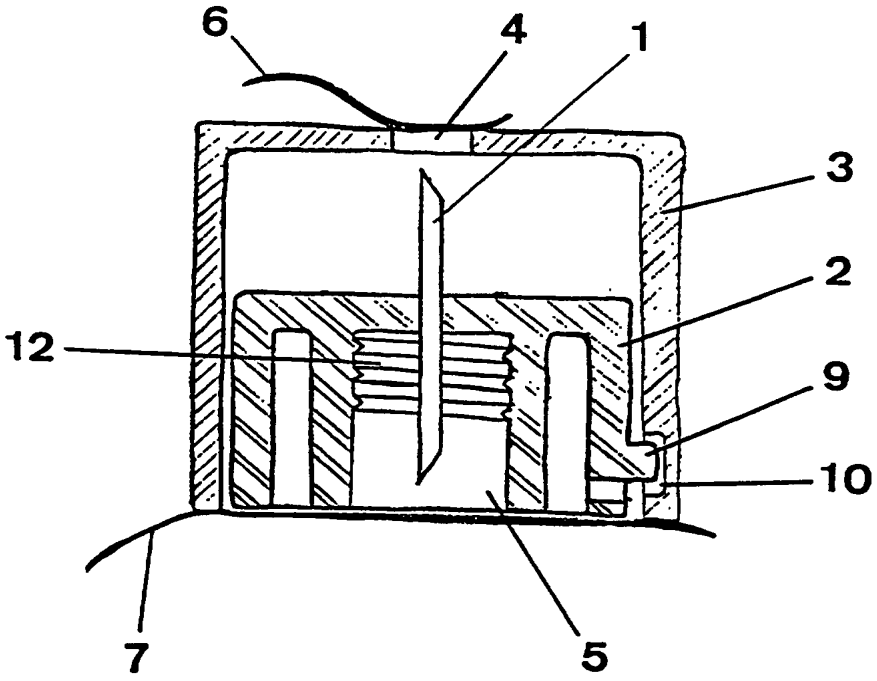


Fig. 1

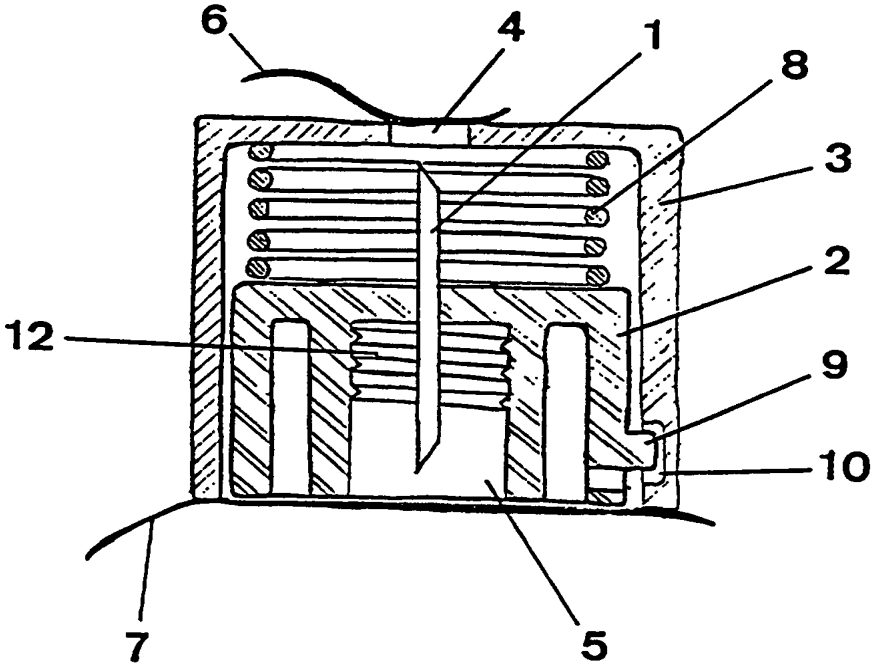


Fig. 2

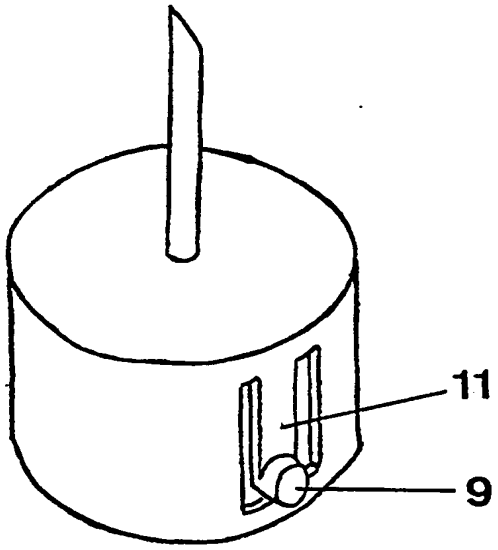


Fig. 3 A

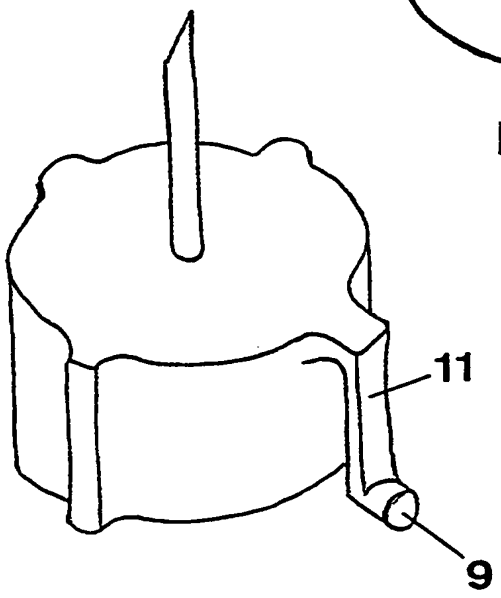


Fig. 3 B

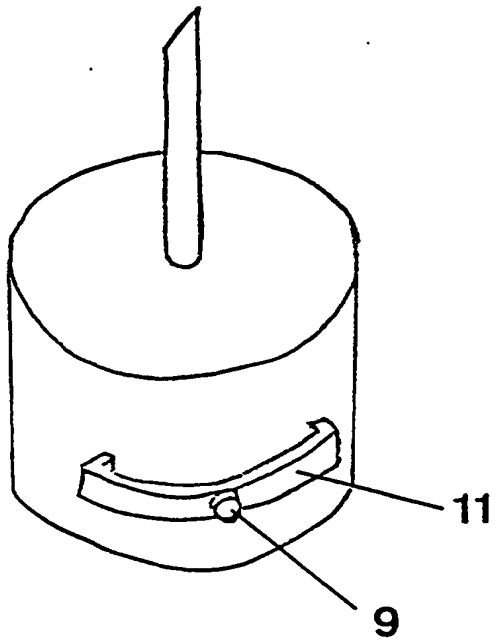


Fig. 3 C

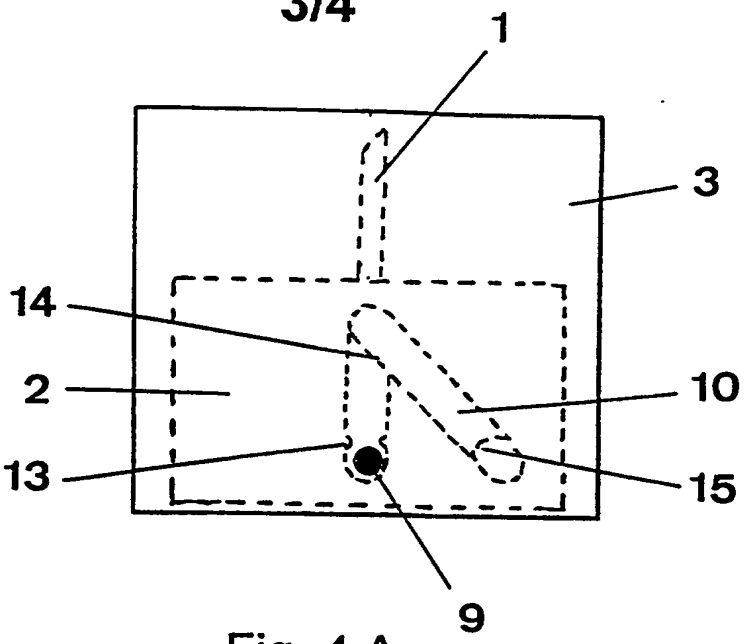


Fig. 4 A

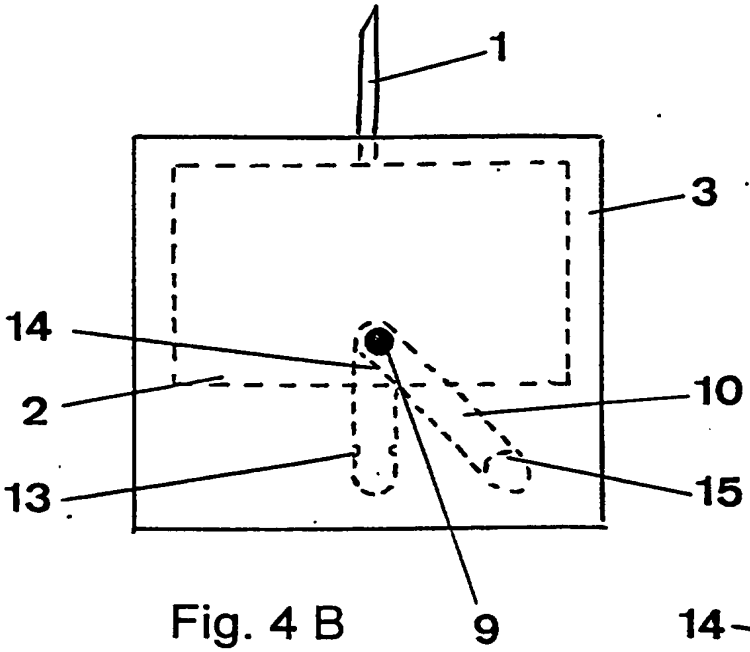


Fig. 4 B

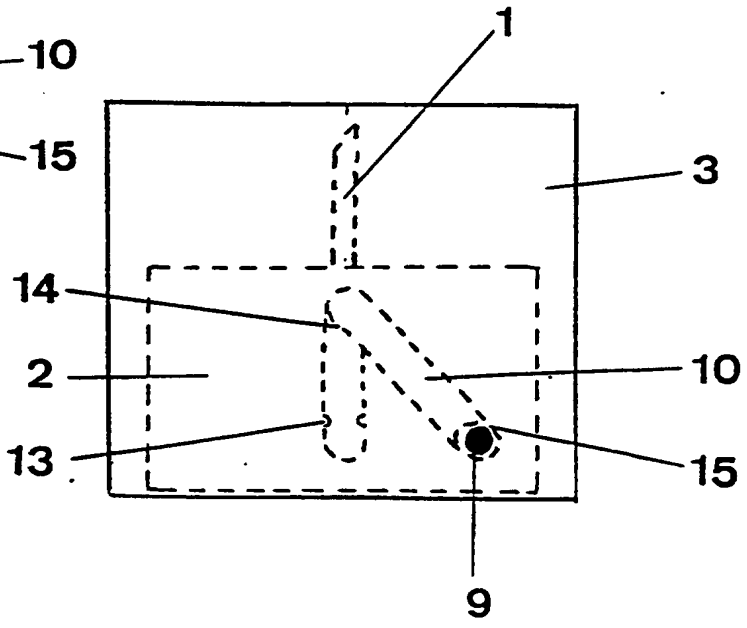


Fig. 4 C

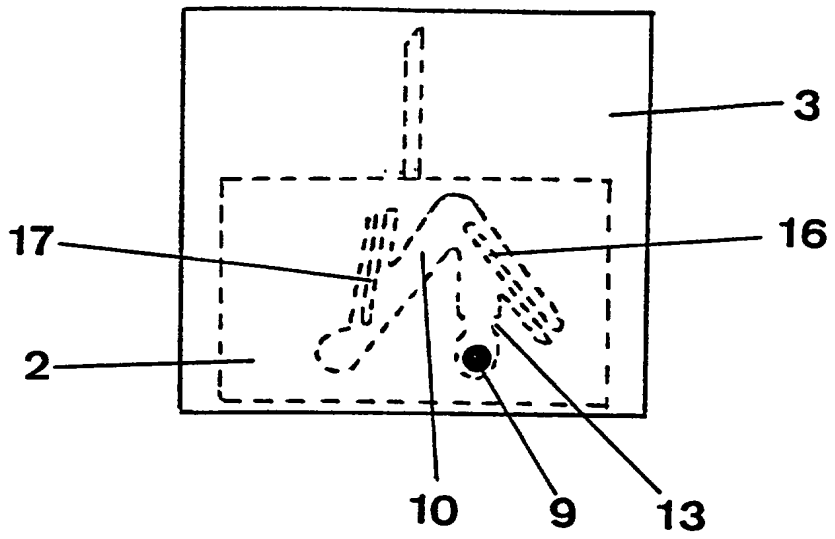


Fig. 5